DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

93732d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS
Our Reference: 2915549

December 6, 2002

Edwin C.S. Noh, Chairman of the Board
E&M Corp. dba Noh Foods of Hawaii
220B Puuhale Road
Honolulu, Hawaii 96819

WARNING LETTER

Dear Mr. Noh:

On August 13-16, and 19, 2002, the U.S. Food and Drug Administration (FDA) inspected your manufacturing facility, E&M Corp. dba Noh Foods of Hawaii, located at 220B Puuhale Road, Honolulu, Hawaii. During the inspection, we collected labels of products that your firm manufactures and distributes for institutional use. Our review of the labels reveals that the products are in violation of sections 402 and 403 of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (21 CFR), as follows:

1. The Noh Foods of Hawaii Japanese Teriyaki (TY28) is misbranded under section 403(i)(2) of the Act and 21 CFR 101.4(a)(1) in that the product label fails to declare all of the ingredients contained in the product. The label on this product reads in part: "Ingredients: sugar, salt, soy bean, starch, powdered ginger, powdered onion, spices and caramel color." During the inspection, FDA noted that calcium silicate was added as an ingredient to the product but not declared on the product label.

   FDA also noted that the Teriyaki (TY28) product contains vegetable oil, which is not included in the ingredient list. 21 CFR 101.4(b)(14) requires that your product label declare the common or usual name of each fat and/or oil used in the product.

   Additionally, your Teriyaki (TY28) product contains [redacted] Brand [redacted] Dried Soy Sauce 21 CFR 101.4(b)(2) requires that the [redacted] Brand Dried Soy Sauce be declared in a manner that lists each of its component ingredients, including wheat and maltodextrin These component ingredients are not listed on your product label.

   The declaration of wheat is of particular concern because it is an allergenic substance. FDA has received an increasing number of reports concerning consumers who have

experienced adverse reactions following exposure to an allergenic substance in foods. For sensitive individuals, the presence of allergens in food is potentially life-threatening. Ingredients that are among the most commonly known to cause serious allergenic responses are milk, eggs, fish, crustacea, tree nuts, wheat, peanuts, soybeans and derivatives of these products.

2. The Noh brand Chinese Lemon Chicken (Seasoning Mix), 48 ozs (3 lbs.), is adulterated under section 402(c) of the Act because the product contains FD&C Yellow No. 5, and the presence of that ingredient is not declared on the product label. You must specifically declare the presence of FD&C Yellow No. 5 in the ingredient statement on your product's label to comply with 21 CFR 74.705(d)(2). The declaration of FD&C Yellow No. 5 as an ingredient is a condition for safe use of this color additive in food products.

   The product is also misbranded under section 403(i)(2) and 403(k) of the Act because FD&C Yellow No. 5 is not declared in the ingredient statement. FD&C Yellow No. 5 is a certified color additive. Under 21 CFR 101.22(k)(1), certified color additives must be individually declared in the ingredient statement by their common or usual names (e.g., FD&C Yellow No. 5). The common or usual name may be abbreviated to omit the "FD&C" prefix and the term "No." (e.g., Yellow 5).

   According to the FDA investigator's report, you promised to apply label stickers declaring the presence of FD&C Yellow No. 5 to the products on hand as soon as you had labels prepared.

The violations listed above are not meant to be an all-inclusive list of deficiencies. You are responsible for ensuring adherence to the requirements of the Act and its implementing regulations, including being vigilant that the products you manufacture and distribute meet all of the applicable statutory and regulatory requirements. Failure to promptly correct these violations may result in regulatory action without further notice, including seizure or injunction.

Almost four months have elapsed since FDA inspection. Please provide a response in writing within fifteen (15) working days of receipt of this letter, stating the actions you plan to take, or have taken, to correct all violations. You may wish to include with your response documentation that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,

Dennis K. Linsley
District Director
San Francisco District

cc: Howard E. Noh, Vice President